

PCT
Patent Cooperation Treaty

Docket No.:	PR60223WO
In re:	SmithKline Beecham Corporation
International Application No.:	PCT/US2004/016124
International Filing Date:	20 May 2004
PCT Invitation to Correct Defects in Int'l App.:	29 July 2004

Title: CHILD RESISTANT BLISTER PACKAGES UTILINZING WALLED STRUCTURES
ENCLOSING MEDICAMENT THEREIN

Commissioner for Patents
BOX PCT/RO/US
Washington, DC 20231

**RESPONSE TO INVITATION TO CORRECT DEFECTS IN THE
INTERNATIONAL APPLICATION**
(PCT Rule 26)

Sirs:

In response to the PCT Invitation to Correct Defects in the International Application, mailed to us on 20 May 2004, we send you the following:

- Copy of Form PCT/RO/106-PCT Invitation to Correct Defects in the International Application.
- New page one of specification with correct spelling of "STRUCTURES"
- New Abstract with correct spelling of "STRUCTURES"
- Copy of Correction to PCT Request faxed to IB-WIPO and USPTO on August 19, 2004.

Respectfully submitted,

Date: August 19, 2004



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Agent for applicant
GlaxoSmithKline
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FAXED
8-19-04

FAXED TO: 703-305-8280
6 pages

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PATENT COOPERATION TREATY

From the RECEIVING OFFICE

PCT

To:
DAVID J. LEVY
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FIVE MOORE DRIVE, PO BOX 13398
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INVITATION TO CORRECT DEFECTS IN
THE INTERNATIONAL APPLICATION

(PCT Articles 3(4)(i) and 14(1) and Rule 26)

due 29 Aug 2004

Applicant's or agent's file reference PR60223WO	Date of mailing (day/month/year) 29 Jul 2004
International application No. PCT/US2004/016124	REPLY DUE within <u>1</u> months/days from the above date of mailing
International filing date (day/month/year) 20 May 2004	
Applicant SMITHKLINE BEECHAM CORPORATION	

1. ☒ The applicant is hereby invited, within the time limit indicated above, to correct, in the international application as filed, the defects specified on the attached:
- ☒ Annex A
 - ☐ Annex B1 (text matter of the international application as filed)
 - ☐ Annex C1 (drawings of the international application as filed)

2. ☐ The applicant is hereby invited, within the time limit indicated above, to correct, in the translation of the international application furnished under Rule 12.3 or 12.4, the defects specified on the attached:
- ☐ Annex A
 - ☐ Annex B2 (text matter of the translation of the international application)
 - ☐ Annex C2 (drawings of the translation of the international application)

Additional observations (if necessary):

HOW TO CORRECT THE DEFECTS?

Correction must be submitted by filing a replacement sheet embodying the correction and a letter accompanying the replacement sheet, which shall draw attention to the difference between the replaced sheet and the replacement sheet. A correction may be stated in a letter only if it is of such a nature that it can be transferred from the letter to the record copy without adversely affecting the clarity and direct reproducibility of the sheet onto which the correction is to be transferred (Rule 26.4).

ATTENTION

Failure to correct the defects will result in the international application being considered withdrawn by this receiving Office (see Rule 26.5 for further details).

A copy of this invitation and any attachments has been sent to the International Bureau

☒ and the International Searching Authority

Name and mailing address of the receiving Office Mail Stop PCT, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 703-305-3230	Authorized officer Theodosia Simpkins Telephone No. 703-305-3676
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The receiving Office has found the following defects in the international application as filed:**1. As to signature of the international application (Rules 4.15, 26.2bis(a) and 90.4), the request:**

- a. ☐ is not signed* by the applicant or, if there is more than one applicant, by at least one of them
- b. ☐ is not accompanied by the statement referred to in the check list in Box No. IX of the request explaining the lack of the signature of an applicant for the designation of the United States of America
- c. ☐ is signed by what appears to be an agent/common representative but:
☐ the international application is not accompanied by a power of attorney appointing him
☐ the power of attorney accompanying the international application is not signed by all the applicants
- d. ☐ other (*specify*):

* Although Rule 4.15 requires that all applicants must sign the request (e.g. including all inventors/applicants for the designation of the United States of America), for the purposes of Article 14(1)(a)(i), if there is more than one applicant, it shall be sufficient that the request be signed by one of them (Rule 26.2bis(a)).

However, the applicant's attention is drawn to the fact that the national law applied by each designated Office may require, in connection with the processing of the international application in the national phase, that the applicant furnish the confirmation of the international application by the signature of any applicant for the designated State who has not signed the request (Rule 51bis.1(a)(vi)).

2. As to indications concerning the applicant* who is entitled, according to Rule 19.1, to file the international application with the receiving Office, the request (Rules 4.4, 4.5 and 26.2bis(b)):

- a. ☐ does not properly indicate the applicant's name (*specify*):
- b. ☐ does not indicate the applicant's address
- c. ☐ does not properly indicate the applicant's address (*specify*):
- d. ☐ does not indicate the applicant's nationality
- e. ☐ does not indicate the applicant's residence

☐ Further observations about indications concerning other applicants (if applicable):

* Although Rules 4.4 and 4.5 require indications concerning the applicant, or if there are several applicants, of each of them, for the purposes of Article 14(1)(a)(ii), if there is more than one applicant, it shall be sufficient that the indications required under Rule 4.5(a)(ii) and (iii) be provided in respect of one of them who is entitled according to Rule 19.1 to file the international application with the receiving Office (Rule 26.2bis(b)).

However, the applicant's attention is drawn to the fact that the national law applied by each designated Office may require, in connection with the processing of the international application in the national phase, that the applicant furnish any missing indication required under Rule 4.5(a)(ii) and (iii) in respect of any applicant for the designated State (Rule 51bis.1(a)(vii)).

3. As to the language of certain elements of the international application, other than the description and claims (Rules 12.1(c) and 26.3ter(a) and (c)):

- a. ☐ the request is not in a language of publication accepted by this receiving Office; (the) language(s) accepted by this receiving Office is/are:
- b. ☐ the text matter of the drawings is not in the language in which the international application is to be published, which is:
- c. ☐ the abstract is not in the language in which the international application is to be published, which is:

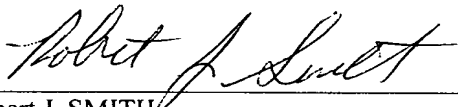
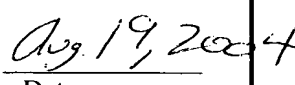
4. The title of the invention:

- a. ☐ is not indicated in Box No. I of the request (Rule 4.1(a))
- b. ☐ is not indicated at the top of the first sheet of the description (Rule 5.1(a))
- c. ☒ as appearing in Box No. I of the request is not identical with the title heading the description (Rule 5.1(a))

5. As to the abstract (Rules 8 and 26.1(b)):

- ☐ the international application does not contain an abstract

Via Facsimile

TO: International Bureau of WIPO 34 Chemin des Colombettes 1211 Geneva 20 Switzerland Fax: 011 41 22 740 1435 And USPTO fax 703-305-3230		Correction to PCT Request before PUBLICATION	
Applicant's File Reference PR60223WO			
International Application No. PCT/US2004/016124		International Filing Date: 20 May 2004	
		Title: CHILD RESISTANT BLISTER PACKAGES UTILIZING WALLED STRUCTURES ENCLOSING MEDICAMENT THEREIN	
<p>Please make the following correction to PCT Request for this case before Publication:</p> <p>On page 1 of PCT Request, line I -Title of Invention: Please correct "STRUCUTRES" to read "STRUCTURES"</p> <p>Please also correct Abstract title to show "STRUCTURES"</p> <p>A <u>corrected</u> copy of the first page of the specification and abstract is attached to request and indicates that this title is correct.</p> <p>Please acknowledge receipt of this request by return fax to (919) 483-7988 in the United States. If there should be questions, please call (919) 483-2252.</p> <p>Thank you.</p>			
<p>Sincerely,</p> <div style="display: flex; justify-content: space-between; align-items: flex-end;"><div style="text-align: center;"> Robert J. SMITH Agent for the applicant</div><div style="text-align: center;"> Date</div></div>			

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8-19-04

**CHILD RESISTANT BLISTER PACKAGES UTILIZING
WALLED STRUCTURES ENCLOSING MEDICAMENT THEREIN**

Field and Background of the Invention

5 The invention generally relates to child resistant blister packages. The child-resistant ("CR") requirement for products packaged in blisters is typically dependent upon the toxicity level of any given product. Currently, the more toxic the drug, the more difficult the opening feature is made to gain access to the product in order to pass Consumer Product Safety Commission ("CPSC") protocol requirements. In
10 cases where a single tablet or capsule is considered harmful to a 25lbs. child, there are very few, if any, options available that are considered "user friendly". The existing options that pass official protocol testing require multiple steps that can be physically challenging and/or require an implement i.e.; scissors to open. Thus, there is a need in the art for a child-resistant blister package that addresses
15 problems associated with the above-mentioned existing options.

Summary of the Invention

 This invention substantially minimizes or prevents children from gaining access in accordance with the above protocol limits while at the same time is
20 capable of opening similarly to a non-CR push through blister design.

 More particularly, the invention provides a child resistant blister package. The child resistant blister package comprises a film having a surface wherein a plurality of cavities are formed therein containing at least one medicament; a cover sheet which overlies the cavities and is attached to the film;
25 and a wall structure raised above the surface of the film which extends throughout the film forming an interior region such that the plurality of cavities are enclosed within the interior region.

 Most children gain access to blister packaged products by biting through the clear blister material. In accordance with the present invention, the presence of the
30 wall structure substantially minimizes or eliminates the probability of a child from gaining access to a blister by penetrating the blister with his or her teeth.

10/506879
DT04 Rec'd PCT/PTO 03 SEP 2004

**CHILD RESISTANT BLISTER PACKAGES UTILIZING
WALLED STRUCTURES ENCLOSING MEDICAMENT THEREIN**

Abstract of the Invention

A child resistant blister package includes a film having a surface wherein a plurality of cavities are formed therein containing at least one medicament; a cover sheet which overlies the cavities and is bonded to the film; and a wall structure raised above the surface of the film which extends throughout the film forming an interior region enclosing the plurality of cavities therein.